

REMARKS

Reconsideration is requested.

Claims 7, 8, 10, 14, 17 and 18 have been canceled, without prejudice. Claims 19-38 have been added as dependent claims similar to claims 3-6 and 9 but dependent from claims 11, 13, 15 and 16. The details of claim 14, which the Examiner has indicated contains allowable subject matter (see, page 8 of the Office Action dated June 25, 2003), have been included in the above amended claims 1 and 2, to at least place claims 1-6 and 9 in condition for allowance.

Moreover, claims 11-13 and 15-16 have been amended to be similar to the amended claim 1 with the recitation of the additional species indicated by the Examiner in the Office Action of September 10, 2002. As the elected species now defines over the cited art, the Examiner is requested to consider the additional species which are now the subject of separate claims 11-13 and 15-16 and allow the same with claims 1-6 and 9. As noted above, claims 19-38 have been added and are similar to claims 3-6 and 9 while being dependent on claims to the additional species of claims 11, 13, 15 and 16. While the above amendments add claims without canceling a corresponding number of claims, entry of the additional dependent claims is not believed to be contrary to the prohibition against adding claims after final rejection without canceling any final rejected claims, as described in MPEP § 714.13 (page 700-205, Rev. 1, Feb. 2003, copy attached) and the cited Ex Parte Wirt, 117 O.G. 599 (Commissioner of Patents 1905) (copy attached). Entry of all the above amendments and consideration and allowance of all the claims are requested.

The Examiner's comments with regard to the inclusion of sequence identifiers in Table 1 on pages 12-15 of the specification are noted. See, page 2 of the Office Action dated June 25, 2003. The Examiner is requested to see the Amendment of April 25, 2003, at page 2, wherein insertion of the new pages 12-15 attached to the Amendment was requested. A clean and marked-up copies of new Table 1, including the sequence identifiers, were attached to the Amendment of April 25, 2003. Further copies of the same along with the undersigned's Post Card of April 25, 2003, acknowledging the Patent Office receipt of the pages to be inserted are attached. The Examiner is requested to advise the undersigned if anything further is required in this regard and/or if the undersigned has misunderstood the Examiner's continued objection.

The Section 103 rejection of claims 1-9 over Gibson (Genome Research (1996) 6:995-1001) in view of WalkerPeach (U.S. Patent No. 6,395,470), will be moot upon the entry of the above amendments. As noted above, the claims have been amended to define the subject matter indicated by the Examiner to be patentable over the art, to advance prosecution and without prejudice. Entry of the above amendments and withdrawal of the Section 103 rejection are requested.

The Section 103 rejection claims 1-10 over Gibson in view of WalkerPeach and Kennedy (Journal of Pathology (1997) 183:447-453), will be moot upon entry of the above amendments. As noted above, the claims have been amended to advance prosecution, without prejudice, and define subject matter indicated by the Examiner as being patentable over the art. Entry of the above amendments and withdrawal of the Section 103 rejection of claims 1-10 are requested.

LOCATELLI et al.
Serial No. 09/831,820
October 27, 2003

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

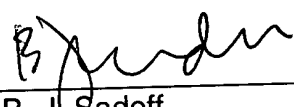
The Examiner is requested to contact the undersigned if anything further is required in this regard.

The Examiner is requested to notify the undersigned of any drawing objections and allow time to file any required corrections as the undersigned's file does not indicate either an acceptance of the drawings or any rejection thereof. Completion of the record in this regard is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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IN THE CLAIMS

Amend the claims as follows.

1. (Currently Amended) A method for the quantitative detection of a target nucleic acid sequence of a HHV-8, ~~nucleic acid (target)~~ from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid (calibrator) previously added to the sample itself, said calibrator ~~having the same sequence of the target nucleic acid~~, said calibrator having i) the same sequence of the target nucleic acid, apart from the region hybridizing to a target the probe, which is randomized with respect to the corresponding region of the target nucleic acid, maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic acid $T_m \pm 4^\circ\text{C}$ with respect to the corresponding region of the target nucleic acid, having the same nucleotide composition, but with a random sequence, and a similar T_m ,

b) mixing the extracted target nucleic acid and calibrator with a forward primer which has the sequence of SEQ ID NO:5, with a reverse primer which has the sequence of SEQ ID NO:6, ~~primers (forward and reverse) annealing to the corresponding regions on the calibrator and on the target nucleic acid~~, with said target probe ~~probes~~ bearing a reporter and a quencher, said target probe having the sequence of SEQ ID NO:7, and a calibrator probe bearing a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:8, and annealing said forward primer, said reverse primer, and said probes bearing a reporter and a quencher to the target nucleic acid and to the corresponding randomized region on the calibrator, and

~~with a~~ in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under in suitable conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity.

2. (Currently Amended) A method for the quantitative detection of a target nucleic acid sequence of a HHV-8, nucleic acid (target) from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid (calibrator) previously added to the sample itself, said calibrator ~~having the same sequence of the target nucleic acid, said calibrator~~ having i) the same sequence as the target nucleic acid, apart from the regions hybridizing to a the probe or to the primers, which are randomized with respect to the corresponding regions of the target nucleic acid, maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic acid $T_m \pm 4^\circ\text{C}$

b) mixing the extracted target nucleic acid and calibrator a forward primer which has the sequence of SEQ ID NO:5, with a reverse primer which has the sequence of SEQ ID NO:6, with primers (forward and reverse) annealing to the target nucleic acid and to the corresponding randomized regions on the calibrator, with a probe probes bearing a reporter and a quencher, said target probe having the sequence of SEQ ID NO:7, and a calibrator probe bearing a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:8, and annealing said forward primer, said reverse primer, and said probes bearing a reporter and a quencher to the target nucleic acid

and to the corresponding randomized region on the calibrator, ~~and with a~~ in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under ~~in suitable~~ conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity.

3. (Previously Amended) Method according to the claim 1, wherein the calibrator T_m is comprised in the $\pm 4^\circ\text{C}$ range of the target nucleic acid T_m .

4. (Previously Amended) Method according to claim 1 wherein the 5' end of the probes is 1 to 30 nucleotides from the 3' end of the forward primer.

5. (Currently Amended) Method according to claim 1, wherein the probe is ~~probes have the~~ 3' end blocked in order to prevent the extension by the polymerase.

6. (Currently Amended) Method according to claim 1, wherein said ~~nucleic acids,~~ ~~said probes and said primers are DNA sequences, and the~~ nucleic acid polymerase is thermostable DNA polymerase with 5' -3' nuclease activity.

Claims 7 and 8 (Canceled).

9. (Currently Amended) Method according to claim 1, wherein said probe ~~probes~~ ~~include~~ includes a quencher label able to reduce or to avoid the reporter label fluorescence when the ~~probes are~~ probe is free in solution.

Claim 10 (Canceled).

11. (Currently Amended) A method for the quantitative detection of a target nucleic acid sequence of a HHV-6, from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid (calibrator) previously added to the sample, said calibrator having i) the same sequence of the target nucleic acid, apart from the region hybridizing to a target probe, which is randomized with respect to the corresponding region of the target nucleic acid, maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic acid $T_m \pm 4^\circ\text{C}$ with respect to the corresponding region of the target nucleic acid, having the same nucleotide composition, but with a random sequence, and a similar T_m ,

b) mixing the extracted target nucleic acid and calibrator with a forward primer which has the sequence of SEQ ID NO:25, with a reverse primer which has the sequence of SEQ ID NO:26, with said target probe bearing a reporter and a quencher, said target probe having the sequence of SEQ ID NO:27, and a calibrator probe bearing a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:28, and annealing said forward primer, said reverse primer, and said probes bearing a reporter and a quencher to the target nucleic acid and to the corresponding randomized

region on the calibrator, in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity. ~~Method according to claim 10, wherein the virus is HHV-6, the forward primer has the sequence 5' GAAAGCCAAATTATCCAGAGCG 3' (SEQ ID NO:25), the reverse primer has the sequence 5' CGCTAGGTTGAGGATGATCGA 3' (SEQ ID NO:26), the target nucleic acid probe has the sequence 5' CACCAGACGTCACACCCGAAGGAAT 3' (SEQ ID NO:27), and the calibrator probe has the sequence 5' TACGCAACGCCAACAGACCTAGCGA 3' (SEQ ID NO:28).~~

12. (Previously Amended) Method according to claim 11, wherein the calibrator is additionally randomised in the regions annealing to primers having the sequences 5' CCGGAAACCGAACATTACTGAA 3' (forward) (SEQ ID NO:29) and 5' TTACGTGAGGATGATCGAGGC 3' (reverse) (SEQ ID NO:30).

13. (Currently Amended) A method for the quantitative detection of a target nucleic acid sequence of a HHV-7, from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid (calibrator) previously added to the sample, said calibrator having i) the same sequence of the target nucleic acid, apart from the region hybridizing to a target probe, which is randomized with respect to the corresponding region of the target nucleic acid, maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic

acid Tm +/-4°C with respect to the corresponding region of the target nucleic acid, having the same nucleotide composition, but with a random sequence, and a similar Tm,

b) mixing the extracted target nucleic acid and calibrator with a forward primer which has the sequence of SEQ ID NO:1, with a reverse primer which has the sequence of SEQ ID NO:2, with said target probe bearing a reporter and a quencher, said target probe having the sequence of SEQ ID NO:3, and a calibrator probe bearing a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:4, and annealing said forward primer, said reverse primer, and said probes bearing a reporter and a quencher to the target nucleic acid and to the corresponding randomized region on the calibrator, in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity. ~~Method according to claim 10, wherein the virus is HHV-7, the forward primer has the sequence 5' AGCGGTACCTGTAAAATCATCCA 3' (SEQ ID NO:1), the reverse primer has the sequence 5' AACAGAAACGCCACCTCGAT 3' (SEQ ID NO:2), the target nucleic acid probe has the sequence 5' ACCAGTGAGAACATCGCTCTAACTGGATCA 3' (SEQ ID NO:3), and the calibrator probe has the sequence 5' TAAGCCCTGACCGCACGGGTATAATACTAA 3' (SEQ ID NO:4).~~

Claim 14 (Canceled).

15. (Currently Amended) A method for the quantitative detection of a target nucleic acid sequence of a HIV-1, from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid (calibrator) previously added to the sample, said calibrator having i) the same sequence of the target nucleic acid, apart from the region hybridizing to a target probe, which is randomized with respect to the corresponding region of the target nucleic acid, maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic acid T_m +/-4°C with respect to the corresponding region of the target nucleic acid, having the same nucleotide composition, but with a random sequence, and a similar T_m.

b) mixing the extracted target nucleic acid and calibrator with a forward primer which has the sequence of SEQ ID NO:9, with a reverse primer which has the sequence of SEQ ID NO:10, with said target probe bearing a reporter and a quencher, said target probe having the sequence of SEQ ID NO:11, and a calibrator probe bearing a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:12, and annealing said forward primer, said reverse primer, and said probes bearing a reporter and a quencher to the target nucleic acid and to the corresponding randomized region on the calibrator, in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity. ~~Method according to claim 10, wherein the virus is HIV-1, the forward primer has the sequence 5' TACTGACGCTCTCGCACC 3' (SEQ ID NO:9), the reverse primer has the sequence 5' TCTCGACGCAGGACTCG 3' (SEQ ID~~

~~NO:10), the target nucleic acid probe has the sequence 5'~~

~~ATCTCTCTCCTTCTAGCCTCCGCTAGTCAA 3' (SEQ ID NO:11), and the calibrator
probe has the sequence 5' ACTCTCAGCGGCATTCTCCTCACTTCTACT 3' (SEQ ID
NO:12).~~

16. (Currently Amended) A method for the quantitative detection of a target
nucleic acid sequence of a CAMV, from a sample, which comprises the following steps:

a) extraction of the nucleic acid from the sample with another nucleic acid
(calibrator) previously added to the sample, said calibrator having i) the same sequence
of the target nucleic acid, apart from the region hybridizing to a target probe, which is
randomized with respect to the corresponding region of the target nucleic acid,
maintaining the same nucleotide composition, and ii) a T_m equal to the target nucleic
acid $T_m \pm 4^\circ\text{C}$ with respect to the corresponding region of the target nucleic acid,
having the same nucleotide composition, but with a random sequence, and a similar
 T_m ,

b) mixing the extracted target nucleic acid and calibrator with a forward primer
which has the sequence of SEQ ID NO:13, with a reverse primer which has the
sequence of SEQ ID NO:14, with said target probe bearing a reporter and a quencher ,
said target probe having the sequence of SEQ ID NO:15, and a calibrator probe bearing
a reporter and a quencher, said calibrator probe having a sequence of SEQ ID NO:16,
and annealing said forward primer, said reverse primer, and said probes bearing a
reporter and a quencher to the target nucleic acid and to the corresponding randomized

region on the calibrator, in the presence of nucleic acid polymerase with 5' -3' nuclease activity, under conditions to carry out a polymerization reaction, and

c) determination of the signal associated with the reporters released due to the 5' polymerase nuclease activity. ~~Method according to claim 10, wherein the virus is CAMV, the forward primer has the sequence 5' GTCTTGCGAAGGATAGTGGGA 3' (SEQ ID NO:13), the reverse primer has the sequence 5' CACGTCTTCAAAGCAAGTGGGA 3' (SEQ ID NO:14), the target nucleic acid probe has the sequence 5' TGGCTCATCCCTTACGTCAGTGGAGAT 3' (SEQ ID NO:15), and the calibrator probe has the sequence 5' ATGGCTACATGCTAGGCATCTGTGTGC 3' (SEQ ID NO:16).~~

Claims 17 and 18 (Canceled).

19. (new) Method according to the claim 11, wherein the calibrator T_m is comprised in the $\pm 4^\circ\text{C}$ range of the target nucleic acid T_m .

20. (new) Method according to the claim 13, wherein the calibrator T_m is comprised in the $\pm 4^\circ\text{C}$ range of the target nucleic acid T_m .

21. (new) Method according to the claim 15, wherein the calibrator T_m is comprised in the $\pm 4^\circ\text{C}$ range of the target nucleic acid T_m .

22. (new) Method according to the claim 16, wherein the calibrator T_m is comprised in the $\pm 4^\circ\text{C}$ range of the target nucleic acid T_m .

23. (new) Method according to claim 11, wherein the 5' end of the probes is 1 to 30 nucleotides from the 3' end of the forward primer.

24. (new) Method according to claim 13, wherein the 5' end of the probes is 1 to 30 nucleotides from the 3' end of the forward primer.

25. (new) Method according to claim 15, wherein the 5' end of the probes is 1 to 30 nucleotides from the 3' end of the forward primer.

26. (new) Method according to claim 16, wherein the 5' end of the probes is 1 to 30 nucleotides from the 3' end of the forward primer.

27. (new) Method according to claim 11, wherein the probe is 3' end blocked in order to prevent the extension by the polymerase.

28. (new) Method according to claim 13, wherein the probe is 3' end blocked in order to prevent the extension by the polymerase.

29. (new) Method according to claim 15, wherein the probe is 3' end blocked in order to prevent the extension by the polymerase.

30. (new) Method according to claim 16, wherein the probe is 3' end blocked in order to prevent the extension by the polymerase.

31. (new) Method according to claim 11, wherein said nucleic acids, nucleic acid polymerase is thermostable DNA polymerase with 5' -3' nuclease activity.

32. (new) Method according to claim 13, wherein said nucleic acids, nucleic acid polymerase is thermostable DNA polymerase with 5' -3' nuclease activity.

33. (new) Method according to claim 15 wherein said nucleic acids, nucleic acid polymerase is thermostable DNA polymerase with 5' -3' nuclease activity.

34. (new) Method according to claim 16, wherein said nucleic acids, nucleic acid polymerase is thermostable DNA polymerase with 5' -3' nuclease activity.

35. (new) Method according to claim 11, wherein said probe includes a quencher label able to reduce or to avoid the reporter label fluorescence when the probe is free in solution.

36. (new) Method according to claim 13, wherein said probe includes a quencher label able to reduce or to avoid the reporter label fluorescence when the probe is free in solution.

37. (new) Method according to claim 15, wherein said probe includes a quencher label able to reduce or to avoid the reporter label fluorescence when the probe is free in solution.

38. (new) Method according to claim 16, wherein said probe includes a quencher label able to reduce or to avoid the reporter label fluorescence when the probe is free in solution.

Table 1

	Primers	Probes
HHV-7	Forward (<u>SEQ ID NO:1</u>)	Standard (<u>SEQ ID NO:3</u>)
	5' AGCGGTACCTGTAAATCATCCA3'	5' ACCAGTGAGAACATCGCTCTAACTGGATCA 3'
	Reverse (<u>SEQ ID NO:2</u>)	Calibrator (<u>SEQ ID NO:4</u>)
	5' AACAGAAACGCCACCTCGAT 3'	5' TAAGCCCTGACCCGACGGGTATAATACTAA 3'
HHV-8	Primers	Probes
	Forward (<u>SEQ ID NO:5</u>)	Standard (<u>SEQ ID NO:7</u>)
	5' GTCCAGACGATATGTGCGC3'	5' CATTGGTGGTATATAGATCAAGTTCCGCCA3'
	Reverse (<u>SEQ ID NO:6</u>)	Calibrator (<u>SEQ ID NO:8</u>)
	5' ACTCCAAAATATCGGCCCGG3'	5' ACTATTCCTCCATGCGGGAATTCGAGCATAGTTG3'

(continued)

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Table 1 (continued)

	Primers	Probes
HIV-1	Forward <u>(Seq 10 No: 9)</u>	Standard <u>(Seq 10 No: 11)</u>
	5' TACTGACGCTCTCGCACC 3'	5' ATCTCTCTCCTTCTAGCCCTCCGCTAGTCAA 3'
	Reverse <u>(Seq 10 No: 10)</u>	Calibrator <u>(Seq 10 No: 12)</u>
	5' TCTCGACGCAGGACTCG 3'	5' ACTCTCAGCGGCATTCTCCTCACTTCTACT 3'
CAMV	Primers	Probes
	Forward <u>(Seq 10 No: 13)</u>	Standard <u>(Seq 10 No: 15)</u>
	5' GTCTTGCGAAGGATAGTGGGA 3'	5' TGCGTCAATCCCTTACGTACGTGGAGAT 3'
	Reverse <u>(Seq 10 No: 14)</u>	Calibrator <u>(Seq 10 No: 16)</u>
	5' CACGTCTTCAAAGCAAGTGGGA 3'	5' ATCGCTACATGCTAGGCATCTGTGTGC 3'

(continued)

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Table 1 (continued)

	Primers	Probes
Myc. T. 1	Forward (<u>SEQ ID NO: 17</u>)	Standard (<u>SEQ ID NO: 19</u>)
	5' AGGAGGAGTGGCGCTGATG 3'	5' ACGAGGAGTCGCTGGCCGATCC 3'
	Reverse (<u>SEQ ID NO: 18</u>)	Calibrator (<u>SEQ ID NO: 20</u>)
	5' ACTCGGCGAGAGCTGCC 3'	5' TCCAGCGTCAGGCGTAGGCAGC 3'
Myc. T. 2	Primers	Probes
	Forward (<u>SEQ ID NO: 21</u>)	Standard (<u>SEQ ID NO: 23</u>)
	5' AGGCGAACCCTGCCAG 3'	5' TCGACACATAGGTGAGGTCTGCTACCCACA 3'
	Reverse (<u>SEQ ID NO: 22</u>)	Calibrator (<u>SEQ ID NO: 24</u>)
	5' GATCGCTGATCCGGCCA 3'	5' ACTACGACTACGGCTGGGATCGACATCGAT 3'

Table 2

HHV-6	Primers	Probes
	Forward (<u>SEQ ID NO: 25</u>) 5' CAAAGCCAAATTATCCAGAGCG 3'	Standard (<u>SEQ ID NO: 27</u>) 5' CACCAGACGTCACACCCGAAAGGAAT 3'
	Reverse (<u>SEQ ID NO: 26</u>) 5' CGCTAGGTTGAGGATGATCGA 3'	Calibrator (<u>SEQ ID NO: 28</u>) 5' TACGCAACGCCAACAGACCTAGCGA 3'
	Calibrator	
	Primer forward (<u>SEQ ID NO: 29</u>) 5' CCGGAAACCGAACATTACTGAA 3'	Probe (<u>SEQ ID NO: 31</u>) 5' TACGCAACGCCAACAGACCTAGCGA 3'
	Primer reverse (<u>SEQ ID NO: 30</u>) 5' TTACGTGAGGATGATCGAGGC 3'	

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a series of separate amendment papers into a single clean version in a single amendment paper. Providing this consolidation of claims in the file will be beneficial to both the Office and the applicant. When rewriting a claim in the clean set, the parenthetical expression, if any, identifying the version of the previous amendment of the claim to be rewritten, should not be repeated in the clean set. If no changes are being made in the amendment presenting the clean set, the paper should be entered. If, however, the amendment includes claims being amended (and is accompanied by a marked-up version showing the changes), the examiner may choose not to enter the amendment in view of matters relating to the provisions of 37 CFR 1.116.

ACTION BY EXAMINER

See also MPEP § 706.07(f).

In the event that the proposed amendment does not place the case in better form for appeal, nor in condition for allowance, applicant should be promptly informed of this fact, whenever possible, within the statutory period. The refusal to enter the proposed amendment should not be arbitrary. The proposed amendment should be given sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Ordinarily, the specific deficiencies of the amendment need not be discussed. The reasons for nonentry should be concisely expressed. For example:

(A) The claims, if amended as proposed, would not avoid any of the rejections set forth in the last Office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

(B) The claims, if amended as proposed, would raise the issue of new matter.

(C) The claims as amended present new issues requiring further consideration or search.

(D) Since the amendment presents additional claims without canceling any finally rejected claims it is not considered as placing the application in better condition for appeal. *Ex parte Wirt*, 1905 C.D. 247, 117 O.G. 599 (Comm'r Pat. 1905).

Examiners should indicate the status of each claim of record or proposed in the amendment, and which proposed claims would be entered on the filing of an

appeal if filed in a separate paper. Whenever such an amendment is entered for appeal purposes, the examiner must indicate on the advisory action which individual rejection(s) set forth in the action from which the appeal was taken (e.g., the final rejection) would be used to reject the new or amended claim(s).

Applicant should be notified, if certain portions of the amendment would be acceptable as placing some of the claims in better form for appeal or complying with objections or requirements as to form, if a separate paper were filed containing only such amendments. Similarly, if the proposed amendment to some of the claims would render them allowable, applicant should be so informed. This is helpful in assuring the filing of a brief consistent with the claims as amended. A statement that the final rejection stands and that the statutory period runs from the date of the final rejection is also in order.

Advisory Action form PTOL-303 should be used to acknowledge receipt of a reply from applicant after final rejection where such reply is prior to filing of an appeal brief and does not place the application in condition for allowance. This form has been devised to advise applicant of the disposition of the proposed amendments to the claims and of the effect of any argument or affidavit not placing the application in condition for allowance or which could not be made allowable by a telephone call to clear up minor matters.

Any amendment timely filed after a final rejection should be immediately considered to determine whether it places the application in condition for allowance or in better form for appeal. An examiner is expected to turn in a response to an amendment after final rejection within 10 calendar days from the time the amendment is received by the examiner. A reply to an amendment after final rejection should be mailed within 30 days of the date the amendment is received by the Office. In *all* instances, both before and after final rejection, in which an application is placed in condition for allowance, applicant should be notified promptly of the allowability of the claims by a Notice of Allowability form PTOL-37. If delays in processing the Notice of Allowability are expected, e.g., because an extensive examiner's amendment must be entered, and the end of a statutory period for reply is near, the examiner should notify applicant by way of an interview that the application has been

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DECISIONS OF THE COMMISSIONER OF PATENTS. 247

ver is of the opinion that there is no interference in fact, he is not without remedy. The provisions of Rule 126 are available when this case comes on for final hearing.

The decision of the Examiner of Interferences is affirmed, and the petition is denied.

MPEP
=14.13
P-20-119

EX PARTE WIRT.

Decided June 27, 1905.

(117 O. G., 599.)

AMENDMENT AFTER FINAL REJECTION—ADDITIONAL CLAIMS—CHANGE IN SUBSTANCE.

Where after final rejection additional claims are presented for the alleged purpose of placing the case in better form for appeal, but no rejected claims are canceled. *Held* that the new claims must be regarded as differing from the rejected claims in substance and not merely in form, and therefore the Examiner's refusal to enter the claims sustained.

ON PETITION.

MAIL-BOX.

Messrs. Bradford & Hood for the applicant.

ALLEN, Commissioner:

This is a petition from the action of the Primary Examiner refusing to admit a claim presented for the purpose of appeal after final rejection.

The applicant made no showing of reasons why the claim was not sooner presented, (Rule 68,) but says that it should be admitted on the ground that it places the claims in better form for appeal. It is to be noted, however, that the claim is not one of those finally rejected in different form, but is a new claim, which the applicant desires considered in addition to the previously-rejected claims. It must differ from each of the rejected claims in other respects than in form, since if there is no difference in substance there is no justification for retaining both claims. The applicant's action in insisting upon both must be taken as an admission that they are not the same in substance. A mere inspection of the claim, furthermore, shows that it is not of the same scope as the rejected claims. Whether or not the grounds of rejection given by the Examiner would apply to this claim as well as to these previously considered cannot be decided. Presumably the Examiner thinks they would not or that it would be necessary for him to make an examination of the case to determine whether or not the best references had been cited for the construction covered by that claim.

The Examiner's action was in accordance with the well-settled practice of the Office.

It appears that the applicant has filed an appeal to the Examiners-in-Chief including the proposed claim as well as the rejected claims.

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The Examiner should forward that appeal with his answer as to the rejected claims and should call attention to the fact that the additional claim has not been entered or acted upon and is not appealable.

The petition is denied.

EX PARTE BUSENBENZ.

Decided June 28, 1905

(117 O. G., 600.)

ABANDONED APPLICATION—INSUFFICIENT ACTION—REQUEST FOR RECONSIDERATION.

Where an applicant at the end of the period allowed him by statute files an amendment, but as to many of the claims merely asks for reconsideration, without pointing out how they are supposed to avoid the references cited, *Held* that he has not taken such action as the condition of the case required and that it is abandoned.

ON PETITION.

GAS-GENERATING APPARATUS.

Messrs. Dyrenforth, Dyrenforth & Lee for the applicant.

ALLEN, Commissioner:

This is a petition from the action of the Primary Examiner holding that the above-entitled application is abandoned.

It appears from the record that this case originally included twenty-two claims, and on December 27, 1901, the Examiner made his first action in the case. On December 19, 1902, an amendment was presented canceling two claims and asking reconsideration of the others on the ground that "they are specific enough to avoid the references." No explanation whatever was made as to how they were supposed to avoid the references, except as to two claims. On January 6, 1903, the Examiner objected to the title of the invention, criticised the form of five claims which were otherwise pronounced allowable, and rejected fifteen claims upon the prior art. A reply to this action was filed December 28, 1903, in which two claims were canceled, an argument was made as to the title of the invention, and it was said that the criticism of the form of the five claims was not understood. As to the remaining thirteen rejected claims it was said:

The remaining claims do not appear to be met by the references.

The Examiner did not regard this as such proper action as the condition of the case required and in a letter of January 12, 1904, held it to be abandoned. On January 9, 1905, the applicant asked reconsideration of that ruling. The ruling was repeated, and this petition was filed June 8, 1905.

It is to be noted that the applicant waited almost the full statutory period before responding to any action by this Office. It is to be noted, further, that more than four years after this case was filed it

arbitrary. The proposed amendment should be given sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Ordinarily, the specific deficiencies of the amendment need not be discussed. The reasons for nonentry should be concisely expressed. For example:

(A) The claims, if amended as proposed, would not avoid any of the rejections set forth in the last Office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

(B) The claims, if amended as proposed, would raise the issue of new matter.

(C) The claims as amended present new issues requiring further consideration or search.

(D) Since the amendment presents additional claims without canceling any finally rejected claims it is not considered as placing the application in better condition for appeal. *Ex parte Wirt*, 1905 C.D. 247, 117 O.G. 599 (Comm'r Pat. 1905).

Examiners should indicate the status of each claim of record or proposed in the amendment, and which proposed claims would be entered on the filing of an appeal if filed in a separate paper.

Applicant should be notified, if certain portions of the amendment would be acceptable as placing some of the claims in better form for appeal or complying with objections or requirements as to form, if a separate paper were filed containing only such amendments. Similarly, if the proposed amendment to some of the claims would render them allowable, applicant should be so informed. This is helpful in assuring the filing of a brief consistent with the claims as amended. A statement that the final rejection stands and that the statutory period runs from the date of the final rejection is also in order.

Advisory Action form PTOL-303 should be used to acknowledge receipt of a reply from applicant after final rejection where such reply is prior to filing of an appeal brief and does not place the application in condition for allowance. This form has been devised to advise applicant of the disposition of the proposed amendments to the claims and of the effect of any argument or affidavit not placing the application in condition for allowance or which could not be made allowable by a telephone call to clear up minor matters.

Any amendment timely filed after a final rejection should be immediately considered to determine whether it places the application in condition for allowance or in better form for appeal. An examiner is expected to turn in a response to an amendment after final rejection within 10 calendar days from the time the amendment is received by the examiner. A reply to an amendment after final rejection

should be mailed within 30 days of the date the amendment is received by the Office. In *all* instances, both before and after final rejection, in which an application is placed in condition for allowance, applicant should be notified promptly of the allowability of the claims by a Notice of Allowability form PTOL-37. If delays in processing the Notice of Allowability are expected, e.g., because an extensive examiner's amendment must be entered, and the end of a statutory period for reply is near, the examiner should notify applicant by way of an interview that the application has been placed in condition for allowance, and an Interview Summary PTOL-413 should be mailed. Prompt notice to applicant is important because it may avoid an unnecessary appeal and act as a safeguard against a holding of abandonment. Every effort should be made to mail the letter before the period for reply expires.

If no appeal has been filed within the period for reply and no amendment has been submitted to make the application allowable or which can be entered in part (see MPEP § 714.20), the application stands abandoned.

It should be noted that under 37 CFR 1.181(f), the filing of a 37 CFR 1.181 petition will not stay the period for reply to an examiner's action which may be running against an application. See MPEP § 1207 for appeal and post-appeal procedure. For after final rejection practice relative to affidavits or declarations filed under 37 CFR 1.131 and 1.132, see MPEP § 715.09 and § 716.

Form paragraphs 7.67-7.80 are to be used when issuing advisory actions after a final rejection.

¶ 7.67 Advisory After Final, Heading, Before Appeal

The period for reply [1] to run [2] MONTHS from the mailing date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 must be timely filed to avoid abandonment of this application.

Examiner Note:

1. This paragraph should appear as a heading in all advisory actions prior to appeal. After appeal, use paragraph 7.68.
2. In bracket 1, insert --continues-- if applicant has not submitted a petition for an extension of time along with the appropriate fee under 37 CFR 1.136. If a proper extension has been requested under 37 CFR 1.136, insert --is extended-- in bracket 1.
3. In bracket 2, insert the full statutory period resulting from any extensions of time which have been granted, e.g., --FOUR-- months.
4. DO NOT USE THIS FORM PARAGRAPH FOR REEXAMINATION PROCEEDINGS.
5. Follow with form paragraph 7.41.01 if transitional provisions of 37 CFR 1.129(a) are applicable.

¶ 7.67.01 Advisory After Final, Heading, 1st Reply Filed Within 2 Months

The shortened statutory period for reply expires THREE MONTHS from the mailing date of the final rejection or as of the mailing date of this

(C) a request for continued examination (RCE) filed under 37 CFR 1.114 with a submission (i.e., an amendment that meets the reply requirement of 37 CFR 1.111) and the fee set forth in 37 CFR 1.17(e). RCE practice under 37 CFR 1.114 does not apply to utility or plant patent applications filed before June 8, 1995 and design applications.

Further examination of the application may be obtained by filing a continued prosecution application (CPA) under 37 CFR 1.53(d), if appropriate. See MPEP § 201.06(d). CPA practice does not apply to utility or plant applications if the prior application has a filing date on or after May 29, 2000. See MPEP § 706.07(h), paragraphs I and IV.

An amendment filed at any time after final rejection, but before an appeal brief is filed, may be entered upon or after filing of an appeal brief provided the total effect of the amendment is to (A) remove issues for appeal, and/or (B) adopt examiner suggestions.

See also MPEP § 1207 and § 1211.

The U.S. Patent and Trademark Office does not recognize "conditional" authorizations to charge an appeal fee if an amendment submitted after a final Office action is not entered. Any "conditional" authorization to charge an appeal fee set forth in 37 CFR 1.17(b) will be treated as an unconditional payment of the fee set forth in 37 CFR 1.17(b).

Applicant may submit an amendment under 37 CFR 1.116 by presenting a clean set of all pending claims in one paper. 37 CFR 1.121(c)(3) provides for the optional submission by applicant of a clean version (with no markings) of all of the pending claims in one amendment paper. Applicants may wish to consolidate all previous versions of pending claims from a series of separate amendment papers into a single clean version in a single amendment paper. Providing this consolidation of claims in the file will be beneficial to both the Office and the applicant. When rewriting a claim in the clean set, the parenthetical expression, if any, identifying the version of the previous amendment of the claim to be rewritten, should not be repeated in the clean set. If no changes are being made in the amendment presenting the clean set, the paper should be entered. If, however, the amendment includes claims being amended (and is accompanied by a marked-up version showing the changes), the examiner may choose not to enter the

amendment in view of matters relating to the provisions of 37 CFR 1.116.

ACTION BY EXAMINER

See also MPEP § 706.07(f).

In the event that the proposed amendment does not place the case in better form for appeal, nor in condition for allowance, applicant should be promptly informed of this fact, whenever possible, within the statutory period. The refusal to enter the proposed amendment should not be arbitrary. The proposed amendment should be given sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Ordinarily, the specific deficiencies of the amendment need not be discussed. The reasons for nonentry should be concisely expressed. For example:

(A) The claims, if amended as proposed, would not avoid any of the rejections set forth in the last Office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

(B) The claims, if amended as proposed, would raise the issue of new matter.

(C) The claims as amended present new issues requiring further consideration or search.

(D) Since the amendment presents additional claims without canceling any finally rejected claims it is not considered as placing the application in better condition for appeal. *Ex parte Wirt*, 1905 C.D. 247, 117 O.G. 599 (Comm'r Pat. 1905).

Examiners should indicate the status of each claim of record or proposed in the amendment, and which proposed claims would be entered on the filing of an appeal if filed in a separate paper. Whenever such an amendment is entered for appeal purposes, the examiner must indicate on the advisory action which individual rejection(s) set forth in the action from which the appeal was taken (e.g., the final rejection) would be used to reject the new or amended claim(s).

Applicant should be notified, if certain portions of the amendment would be acceptable as placing some of the claims in better form for appeal or complying with objections or requirements as to form, if a separate paper were filed containing only such amendments. Similarly, if the proposed amendment to some of the claims would render them allowable, applicant